



Date: March 29<sup>th</sup>, 2021

Monet Vela  
Office of Environmental Health Hazard Assessment  
1001 I Street, 23<sup>rd</sup> Floor  
P. O. Box 4010  
Sacramento, California 95812-4010

Dear Mrs Vela,

Beckman Coulter like to comment on the proposed labeling amendments to Article 6 on the clear and reasonable warning of California Proposition 65 (The Safe Drinking Water and Toxic Enforcement Act of 1983).

Background on Beckman Coulter Inc:

Beckman Coulter, which is headquartered in Brea California, is an operating company of the Danaher Corporation (DHR). DHR incorporates a family of companies in industries such as Diagnostics, Life Sciences, Dental Care as well as Environmental and Applied Solutions (e.g. water quality analysis). Beckman Coulter serves both the fields of Clinical Laboratory Diagnostics and Life Science Research.

As an industry leader with more than 80 years of product experience, Beckman Coulter plays a vital role in optimizing the workflows of diverse laboratories and healthcare institutions, supporting the advancement of scientific research and patient care worldwide. More precisely, the company's contribution to healthcare and research industries are made through the supply of a comprehensive range of sampling, screening, characterization and diagnostic technologies as well as dedicated instrumentation, data management tools and proven process management expertise. These products aim to provide physicians and clinicians with key information on patients' conditions and provide researchers with precision tools to study complex biological problems such as causes of disease and potential new treatments. The company ultimately engages with the core goals of the world's medical practices, hospitals and health networks: Delivering high-quality patient care, improving the health of populations and reducing the costs of healthcare

Reason to Rescind:

OEHHA's Proposed Amendments to Article 6 Clear and Reasonable Warnings – Gov. Code Section 11346.3(b)) (<https://oehha.ca.gov/media/downloads/crn/p65shortformisorf2021.pdf>)

– Cost Impacts on Representative Person or Business: OEHHA is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed regulatory action. The action does not impose any new requirements upon private persons or businesses. Instead, it modifies an existing, non-mandatory safe harbor warning method.

We disagree with the published comments; this amendment would create unnecessary burden and increased costs to all businesses. In Beckman Coulter's situation, our product portfolio already complies with EPA's

Toxic Substance Control Act (TSCA), Hazard Communication Standard, Interstate Mercury Elimination Clearinghouse (IMERC), Battery, Packaging, Registration, Evaluation, Authorization of Restricted Substances (REACH) and Restriction of Hazardous Substances (RoHS) directives as well as the current Proposition 65 requirements.

Requiring a change of labeling from the short-form to the long-form would require a redesign of multiple label(s), added costs for lab testing thousands of parts to determine if any contain one of the nearly 900 substances on the list. The increment costs of testing, label design, design change order, procedures, etc activities and implementation would increase the standard cost of products. These costs would have to be passed onto the consumer, making it more expensive to purchase the same product in the state of California. We don't see that converting to the long-form calling out a substance or substances will reduce over-warning or provide more clear and reasonable warnings about Cancer and Reproductive Harm risks to better protect health and safety of Californians.

We view that identifying the specific Prop 65 chemical in addition to the relevant toxicological endpoint is redundant; serves no useful purpose in a short-form warning; and is not required by the statute. As mentioned, various regulations already require several types of health and safety warnings, which overlap with Prop 65 warning content. Under Prop 65, Section 25249.6. "no person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual." In other words, Prop 65 requires businesses to provide a "clear and reasonable" warning to Californians about significant exposures to chemicals known to the state to cause cancer or reproductive toxicity. The clear and reasonable warning does not require disclosing which specific carcinogens/reproductive toxicants are in the product but rather to warn about the exposure to carcinogen or reproductive toxicant. OEHHA determined that the current short-form warning serves such purpose back in 2016. With this proposal, OEHHA is contradicting its previous determination of the legislative intent.

We also see this proposed change as conflicting with the environmental regulatory policies of California. In particular, the proposed changes do not align with the initiatives under the California Climate Investments (<http://www.caclimateinvestments.ca.gov/about-cci>) and the former Governor Brown's Executive Order to become carbon neutral by 2045 (<https://www.ca.gov/archive/gov39/wp-content/uploads/2018/09/9.10.18-Executive-Order.pdf>). Changing numerous product labels to include the long-form warning would require an increase in packaging size. Replacing labels altogether also increases the carbon footprint to become compliant with the proposed amendment.

California has not presented any substantial evidence that Prop 65 has reduced the number of Cancers and illnesses related to Reproductive Harm during its existence for more than three decades as discussed in this report by the Center for Accountability in Science, a project of the nonprofit Center for Organizational Research and Education (CORE): <https://www.accountablescience.com/wp-content/uploads/2018/06/2018-Proposition-65-State-Impact-Report.pdf>.

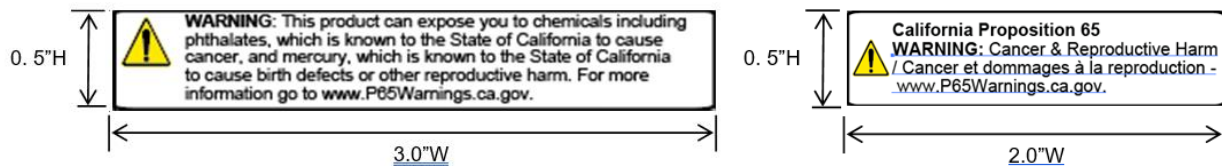
According to the U.S. Centers for Disease Control and Prevention, California's rate of seven common cancers, including Non-Hodgkin's lymphoma, and ovarian, testicular, and stomach cancers, are either no different from or higher than the national average. For reproductive illnesses, the National ART Surveillance System reports that California has among the highest percentage of births requiring assisted reproductive technology, and the National Birth Defects Prevention Network reports that the state faces higher than average rates of central

nervous system defects, and certain cardiovascular and musculoskeletal defects in infants. While businesses have been forced into providing warnings, dealing with Prop 65 litigation, or frequently reformulating products that contain a negligible amount of a listed chemical, there is no substantial evidence that Prop 65 has had a measurable benefit to public health. On the same note, OEHHA's ISR does not provide any support on how this amendment will affect health benefits to Californians.

Therefore, Beckman Coulter requests rescinding the proposal as written.

If OEHHA's final decision is to impose new warning notifications, please consider these recommendations:

- A. Keep the existing warning notification and upon request from the consumer/end-user, disclose a Carcinogen and/or Reproductive toxicant
- B. Extend the enforcement date to a minimum of 7 years for Medical Devices that are used by professionals and operated within a controlled environment. Any labeling changes to a product affect country registration, requires notification to enforcement bodies like FDA, etc.
- C. Increase the total maximum surface area for a short form warning from 5 square inches to at least 20 square inches and define "label space".
- D. Enlarge the total maximum surface area for a short-form warning to at least 20 square inches
  - a. Twenty square inches is still a very small label space considering all the other required labeling elements, such as the product identifier, content information, net quantity or volume, instructions for use, and any other safety warnings or precautions. Five square inches is simply impractical to include all those elements and display the proposed short-form warning in 6 point font size. To illustrate the impracticality, let's consider the current Prop 65 requirements. The minimum short-form label size is an inch square, and the minimum long-form label must be an inch and a half square. These dimensions do not account for other required label content.



Displaying all the other label elements in 3.5 to 4 inch square of remaining space seems extremely difficult if not infeasible. Compliance with the proposed changes becomes more difficult if other languages appear on the labels, notably French and Spanish, because Prop 65 warning needs to be in those languages also. Based on our calculation and estimate, the minimum surface area for a short-form warning should be at least 20 square inches to be reasonable.

We provide these recommendations based on the following reasons:

1. We disagree with the statement in Article 6 Clear and Reasonable Warnings – Gov. Code Section 11346.3(b)) that there will be no cost impact to businesses.
2. The addition to include substance name(s) will require new label designs, additional testing and increased the cost of the product to the consumer/end-user.
3. The transition period of one year is not feasible especially for the Medical Device industry where our products are highly regulated.

In addition, the proposed changes do not provide clear guidance on some requirements. We ask you to please provide some clarification on the following items:

- standards for round products, bagged products, and other irregularly shaped packaging where labels are required but may wrap around the product and limit visibility;
- liability for repackaging products produced by another entity; and
- a definition of what is included in label space to accurately design compliant labels.

The primary driver for high use of Prop 65 warnings is citizen enforcement, and companies risk litigation from citizen-enforcers if they do not provide safe-harbor warnings. The current short-form warning minimizes risks stemming from the civil enforcement provisions. The proposed amendments will not eliminate “over-warning,” and may not significantly decrease the use of such warnings. Most companies will not remove a Prop 65 warning unless they are certain that there are no subject chemicals in their product and there is no Prop 65 litigation risk.

If the proposed changes are finalized as written, businesses would lose their safe harbor and will be exposed to heightened risk of private enforcement. Rather than changing the content of warning labels, especially within such a short time from the August 2018 enforcement date. OEHHA should revamp the regulation to provide more protection to companies that based on a sound scientific approach have made reasonable determinations that warning labeling is not required. This additional protection would drastically decrease the number of monthly prosecutions.

The proposed amendments will cause substantial burdens to companies. With over 900 substances on the Prop 65 list, many products marketed in California are potentially in scope and require resources to assess and test. In addition to these costs, IT (information technology) and ERP (enterprise resource planning) systems would require updates to accommodate a myriad of custom labels for various chemicals that would need to be disclosed on the warning.

If companies incur increased costs to sell products into California because of the resulting label changes, these companies will likely choose to pass these costs onto end users. As a result, Californian consumers will be at a disadvantage compared to similarly situated consumers in other states.

Beckman Coulter appreciates the opportunity to provide input to this important process. We strongly support OEHHA’s efforts to protect health and safety of Californians. Should you have any questions or require any additional information, please contact me at [peter.gonzalez@beckman.com](mailto:peter.gonzalez@beckman.com).

With kind regards,  
Peter Gonzalez  
Product Environmental Compliance